K011910

JUL 1 3 2001

510(k) SUMMARY

Submitter's Name:	American Medical Systems, Inc.
Address:	10700 Bren Road West Minnetonka, MN 55343
Tel:	952-933-4666
Fax:	952-930-6157
Contact Person:	Elsa A. Linke
Date of Summary Preparation:	June 18, 2001
Device Common Name:	Bone Screw Inserter & Bone Screws
Device Trade Name:	In-Fast Bone Screw System
Device Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue Classification: Class II Product Code: MBI
Predicate Device:	In-Fast Bone Screw System K970292

Device Description

The In-Fast Bone Screw System is intended for soft tissue fixation to the pubic bone by means of bone screws threaded with suture. It consists of a transvaginal inserter and bone screws with attached suture.

Indications for Use

The In-Fast Bone Screw System is intended for soft tissue fixation to the pubic bone by means of bone screws with attached suture. The In-Fast System is indicated for cystourethropexy and vaginal sling procedures for the treatment of stress type (female) urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Comparison to Predicate Device

The fundamental scientific technology of the device does not change with this modification. The only material change is the addition of braided suture to the device system.

[510(k) Summary continued]

Supporting Information

The mechanical properties of the braided suture have been tested on the bench for compatibility with the In-Fast system. The suture complies with the USP Monograph for Non-Absorbable Sutures.

Conclusion

The proposed modification is equivalent to the predicate with respect to intended use, technological characteristics, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2001

Ms. Elsa A. Linke
Regulatory Affairs Specialist
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K011910
Device Name: In-Fast Bone Screw System
Regulation Number: 21 CFR 888.3040
Regulatory Class: II
Product Codes: HWC, MBI, GAS
Dated: June 18, 2001
Received: June 19, 2001

Dear Ms. Linke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Milhem

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE ENCLOSURE

510(k) Number: K011910

Device Name: In-Fast Bone Screw System

Indications for Use: The In-Fast Bone Screw System is intended for soft tissue fixation to the pubic bone by means of bone screws with attached suture. The In-Fast System is indicated for cystourethropexy and vaginal sling procedures for the treatment of stress type (female) urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of General and Restorative Devices

510(k) Number _____

Prescription Use X
(Per 21 CFR801.109)

OR

Over the Counter Use _____

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011910